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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/971,980	10/04/2001	David B. Weiner	UPN-4105	4113

34132 7590 09/16/2003

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EXAMINER

CHEN BROWN, STACY

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 09/16/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/971,980

Applicant(s)

WEINER ET AL.

Examiner

Stacy B Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29,31,33,35,46,47,49-51 and 54-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29,31,33,35,46,47,49-51 and 54-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

1. Applicant's amendment dated July 11, 2003 is acknowledged and entered. Claims 29, 31, 33, 35, 46, 47, 49, 50, 51, 54-58 are pending and examined.
2. The objection to claim 55 is withdrawn in view of Applicant's amendment.

Claim Rejections - 35 USC § 103

3. Claims 29, 31, 33, 35, 46, 47, 49, 50, 51, 54-58 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Tardei *et al* (*J. Clin. Micro.*, 38:2232-2239, June 2000) in view of Khromykh *et al* (*J. Virol.*, 72:5967-5977, July 1998) and Houghton *et al* (5,350,671) for reasons of record.

Applicant mainly argues that:

- Houghton only refers to using the C protein as a diagnostic for HCV, not other flaviviruses.
 - In response, Houghton teaches that the flavivirus model for HCV allows predictions regarding the likely location of diagnostic epitopes, such as C, pre-M, M and E (col. 37, lines 60-65). Therefore, Houghton provides motivation and a reasonable expectation of success that the C protein is useful as a diagnostic for HCV and flaviviruses.
- One would not expect the C protein from HCV and WNV to function similarly as a diagnostic because they share only 16% amino acid sequence identity.
 - In response, the Office recognizes the degree of sequence similarity between the C protein from HCV and WNV. However, the rejection is

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based on the prior art's teaching to use a C protein as a diagnostic among flaviviruses. The rejection is not based on a suggestion to use HCV's C protein in a WNV assay.

- Claim 29 is not obvious because none of the references teach an assay where antibodies are used to detect antigen from a sample.
 - As evidence and motivation that assays can be done either with antigen or antibody, Houghton teaches that antibodies can be directed toward epitopes of viral antigens, and that antigens can be directed to antibodies (col. 36, lines 42-54 and lines 61-68). It is a well known feature in the art of immunoassay to detect antigens or antibodies. Since both the antigens and antibodies of WNV are known and ELISAs are known for detecting either antibodies or antigens, it would have been obvious and well within the ability of one of ordinary skill to switch the antigen for the antibody, and vice versa.

Conclusion

4. No claim is allowed.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 308-4426. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy B. Chen, whose telephone number is (703) 308-2361. The Examiner can normally be reached on Monday through Friday from 7:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SBC

Stacy B. Chen
September 10, 2003

James C. Housel
9/16/03

JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
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